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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3762	12

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,225	ERICKSON ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/31/03 (Amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction

1. Newly submitted claim 14 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Independent claim 14 has the following limitations not found in independent claims 1, 4, 6, 8, and 11: "at least one waisted region", "a first electrode and a second electrode", and "wherein the waisted region is positioned between the first electrode and the second electrode.

Since the Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 14 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

2. The Applicant's arguments filed 10/31/03 have been fully considered. The arguments regarding the:

35 U.S.C. 102(b) rejection as being anticipated by Yoon (US 5484426),

35 U.S.C. 102(b) rejection as being anticipated by Clark et al. (EP 0 215 726),

35 U.S.C. 102(e) as being anticipated by Kohnen et al. (US 6249707), and

35 U.S.C. 102(e) rejection as being anticipated by Loeb (US 6112124)

are convincing, hence these rejections are withdrawn.

Additional arguments presented by the Applicant relating to the other rejections are addressed in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

3. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al. (US 6161047). King et al. disclose a stimulation lead (figures 1, 2A, 10A and 10B; col. 3 @ 51-57 and 60-67; col. 6 @ 54-62; col. 7 @ 20-32; col. 10 @ 50-55).

The Applicant argues King et al. fails to provide a lead where the greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure. The Examiner disagrees. In the instant specification, paragraphs 0015 and 0038, the narrow transverse dimension of the lead body is provided to enable percutaneous implantation. King et al. teach a compacted lead position (figure 10A) where the greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure to enable implantation (col. 10 @ 50-55).

The Applicant argues King et al. fails to disclose the lead body has a varying transverse dimension enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead and fails to provide steerablilty of the lead. The Examiner disagrees. King et al. teach the lead body has a varying transverse dimension, transverse by virtue of the spans both in the compacted position (figure 10A) and natural position (figure 10B), hence enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead, providing more rigidity in the plane at the points of the spans and less rigidity in the plane between the spans. King et al. teach the lead body is steerable enabling easy insertion using a catheter/ needle / insertion tool (col. 3 @ 51-57). When the lead body does not have adequate structural support for steering, King et al. teach lead deployment using a stylet (25) (col. 7 @ 20-32).

4. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuzma et al. (US 6522932). Kuzma et al. disclose a paddle-type electrode for spinal stimulation (figures 3, 7A, 7C and 11A; abstract; col. 2 @ 8-22; col. 6 @ 42-46 and 63-66).

The Applicant argues Kuzma et al. fails to provide a lead where the greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure. The Examiner disagrees. In the instant specification, paragraphs 0015 and 0038, the narrow transverse dimension of the lead body is provided to enable percutaneous implantation. Kuzma et al. teach a lead in an insertion structure (50) (figure 7C) where on insertion the greatest transverse dimension of the lead body is less than a corresponding interior dimension of the percutaneous introduction structure (col. 6 @ 42-46).

The Applicant argues Kuzma et al. fails to disclose the lead body has a varying transverse dimension enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead and fails to provide steerablilty of the lead. The Examiner disagrees. Kuzma et al. teach the lead body has a varying transverse dimension, transverse by virtue of the columns of electrodes (figure 7A - 42a, 42b), hence enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead. Kuzma et al. teach the lead body is steerable enabling deployment using an insertion tool (50) and proper material of construction for the lead body as the lead moves into position in the spinal cavity (col. 6 @ 59-62). When the lead body configuration does not have adequate structural support, Kuzma et al. teach lead deployment using a stylet (54) (col. 6 @ 63-66).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102 and 103

6. Claims 1-13 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Errico et al. (US 6175769) in view of Kohnen et al. (US 6249707).

Errico et al. disclose a spinal cord electrode assembly (figures 1 and 3; col. 2 @ 56-63; col. 3 @ 41-52; col. 4 @ 46-50). Errico et al. disclose the art of spinal lead implantation has progressed from an invasive procedure to use of percutaneous positioning (col. 1 @ 22-34). When using percutaneous positioning, Errico et al. identified the lack of lead stabilization as an issue (col. 1 @ 40-46), and disclosed a method to reduce migration of the lead/ electrodes when

using percutaneous positioning (col. 2 @ 9-12), hence the lead is read to be implanted percutaneously. It is accepted that percutaneous positioning includes passing the lead through an insertion structure.

In the alternative, it is well known in the spinal stimulation art to use a percutaneous introduction structure and percutaneous lead positioning to implant a spinal stimulation lead non-surgically. Kohnen et al. disclose non-surgical spinal lead implantation using an apparatus, a percutaneous introduction structure (figure 3 – 15), and method for percutaneously implanting the lead (col. 4 @ 64 – col. 5 @ 18). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used percutaneous lead positioning and a percutaneous introduction structure in the Errico et al. system in order to provide a minimally invasive means for lead insertion that requires only local anesthetics and minimizes the recovery issues/ complication typically associated a surgical spinal lead implantation procedure (Errico et al. – col. 1 @ 28-29 and 32-34; Kohnen et al. - figure 3; col. 1 @ 54 – col. 2 @ 16; col. 4 @ 64 – col. 5 @ 18).

The Applicant argues Errico et al. fails to provide a lead where the greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure. The Examiner disagrees. In the instant specification, paragraphs 0015 and 0038, the narrow transverse dimension of the lead body is provided to enable percutaneous implantation. Errico et al. focus the invention to optimize lead stabilization following percutaneous positioning (col. 1 @ 22-34; col. 2 @ 9-12), percutaneous positioning being accepted to include passing the lead through an insertion structure, hence requiring that the

greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure (Errico et al. – figures 1, 2;

Kohnen et al. - col. 4 @ 64 – col. 5 @ 3).

The Applicant argues Errico et al. fails to disclose the lead body has a varying transverse dimension that enables flexibility in a plane substantially parallel to the principle surface of the body of the lead and fails to provide steerablilty of the lead. The Examiner disagrees.

Errico et al. teach the lead body has a varying transverse dimension, transverse by virtue of the laterally extending portions (figures 1,2 - 101), hence enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead. Errico et al. teach the lead body is steerable based on proper material of construction for the lead body (col. 1 @ 55-60). When the lead body configuration does not have adequate structural support for steerablity, Errico et al. teach lead deployment using a rigid wire/ stylet (col. 4 @ 46-50).

Statutory Basis

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

The Applicant's amendment/ clarification of 35 U.S.C. 112 issue necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
1/16/04

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